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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,278	07/30/2003	Tao Wang	GY-85B CIP2	8698

23914 7590 04/20/2004

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EXAMINER	
BERNHARDT, EMILY B	

ART UNIT	PAPER NUMBER
1624	

DATE MAILED: 04/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/630,278	WANG ET AL.	
	Examiner	Art Unit	
	Emily Bernhardt	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-93 is/are pending in the application.

4a) Of the above claim(s) 62,64,66,91 and 93 is/are withdrawn from consideration.

5)☐ Claim(s) - is/are allowed.

6)☒ Claim(s) 1-61,63 and 65 is/are rejected.

7)☒ Claim(s) 67-90 and 92 is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 12/5/03.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-61, 63, 65,67-90 and 92, drawn to compounds, simple compositions and use, classified in class 544, subclasses such as 238,295,362,etc.; class 514 subclasses such as 252.02 253.04,etc.

II. Claims 62,64 ,66,91 and 93, drawn to complex compositions and use employing I and additional active ingredients, classified in class 514, subclasses various as may determined by specific active ingredient(s) employed.

The inventions are distinct, each from the other because of the following reasons:

Groups I and II are independent and distinct because simple compositions of I may be old or obvious but II may be patentable due to superior or synergistic properties not present in the individual compounds of group I. Subject matter of group II also requires additional consideration for compliance with 35 USC 112, most notably the question of sufficiency of dosage regimens that are commensurate in scope with all pairs of active ingredients embraced for treating HIV and additional viruses embraced.

During a telephone conversation with Mr.Duboff on 4/12/04 a provisional election was made with traverse to prosecute the invention of I, claims 1-61,63 and 65. Affirmation of this election must be made by applicant in replying to this Office action. Claims 62, 64, 66,91 and 93 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicant is reminded of the proper content of an Abstract of the Disclosure.

In chemical patent abstracts for compounds or compositions, the general nature of the compound or composition should be given as well as its use, *e.g.*, "The compounds are of the class of alkyl benzene sulfonyl ureas, useful as oral anti-diabetics." Exemplification of a species could be illustrative of members of the class. For processes, the type reaction, reagents and process conditions should be stated, generally illustrated by a single example unless variations are necessary.

Complete revision of the content of the abstract is required on a separate sheet.

The abstract of the disclosure is objected to because it does not depict a chemical formula showing the basic structural makeup of applicants' compounds. Correction is required. See MPEP § 608.01(b).

Claims 1-61,63 and 65 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. The designation of "F" as an optional substituent in the B definition is misleading since applicants are not using "F" in the art-accepted sense- i.e meaning fluorine but rather as another variable. To avoid confusion in the claims , "F" when **first** recited (in claim 1 on p.3,2nd line) should be immediately followed by wording such as " as defined below".

2. "Thioalkoxy" in the "F" definition is not clear as to structural makeup. See definition given for thioalkoxy in specification on p.47. Are applicants claiming alkylthio or are the S-alkyl, S-cycloalkyl groups mentioned in the specification really alkylthioalkoxy,cycloalkylthioalkoxy? Other terms in the claims such as sulfinyl,sulfonyl are clearly open-ended as recited yet specification provides the missing moiety. "Cyclic N-lactam" is never defined as far as the examiner can determine. Thus its point of attachment and structural makeup is unknown. Is the N atom part of the cyclic ring and/or what othe ring members can be present? Note In

re Wiggins 179 USPQ 421. Note In re Hill 73 USPQ 482 regarding the distortion of art-recognized terms. Applicant should clearly recite what they really mean.

3. "Sulfonamide" is a class of compound not a monovalent moiety as recited in the G definition. Thus how is it attached and what is it structural makeup?

4. Claims 34-38 are incomplete as recited since they do particualarly point out the invention by naming species so that one reading the claims can ascertain its scope but rather resorts to Tables in the specification which is improper. Note reliance on the specification to define claimed subject matter is permitted only under certain circumstances as discussed in Ex parte Fressola 27 USPQ 2d 1608.

Claims 1-33, 39-61,63 and 65 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for the following reasons:1) Specification provides no adequate support teaching how to use **representative** scope of instant compounds corresponding to **"A"** choices being claimed which embraces heteroaryls such as triazines, various azoles and oxazoles as well as bicyclic ring systems **coupled** with an array of functional groups permitted at every ring location for all the R variables, and B-G for 4

isomeric pyrrolo-pyridines which includes hetero rings that are aromatic, as well having other degrees of unsaturation and being mono and polyfused with further substitution thereon which includes more hetero rings which in turn can be further substituted. Compounds made and tested represent the scope of A as phenyl and pyridyl with Q ring system containing (hetero ring) substituents B recited in claims such as 31 with further substitution on said B of the scope in claim 32 (except for "heteroaryl" recited therein). When not heteroaryl, B as phenyl with halo,alkoxy,carboxy or methylenedioxy or B as a carbamoyl group with H, alkyl, alkoxy,benzyl,pyridyl,or thiazolyl or B as lower alkyl, vinyl has been made and tested. However not all of the compounds listed in the Tables have been indicated as tested and no clear evaluation of even the limited data is seen regarding its relevance to in vivo efficacy . There is no reasonable basis for assuming that the myriad of remaining compounds which easily totals in the billions embraced by the generic claims will all share the same physiological properties since they are so structurally dissimilar as to being chemically and biologically non-equivalent and there is no basis in the prior art for assuming the same. Note In re Surrey 151 USPQ 724 regarding sufficiency of disclosure for a Markush group. Also see MPEP 2164.03 for enablement requirements in cases directed to structure-sensitive arts such as the pharmaceutical art. Also note the criteria for enablement as set out

in In re Wands cited in MPEP 2164.01(a),August 2000 edition. Thus given the breadth of the claims, the level of unpredictability in the art and the lack of direction (i.e. working examples) provided as to what other derivatives might work, this rejection is being applied.

2. Method claim 63 embraces treating no one particular virus but rather any and all classes of viruses for which there is no enabling disclosure. Anti-virals tend to be specific toward certain viruses, not an entire class. Note the pages of Drug Evaluations provided in parent which evidences the difficulty in treating viruses in general. Testing in specification appears to be drawn to efficacy against HIV.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (e) the invention was described in-
> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claims 1,2,54-61,63 and 65 are rejected under 35 U.S.C. 102(e) as being anticipated by Wang (WO'255, provided by applicants or US '034). Wang (WO and US) having a different inventive entity than herein and applied as of its earlier

provisional priority date of 2/22/00 discloses several compounds within the instant scope for treating HIV in particular. See species in Tables (such as 11a-11c, 17a-17d) beginning on page 54 through 57 of the WO document and cols.41 and 43 of the US patent.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 3-5,7-15,47-49, and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang (WO'255 or US'034). The teachings of Wang as applied above in the 102 rejection is incorporated herein. Compounds embraced in claims rejected herein differ from species pointed out in the above 102 rejection only in nature of substitiuent on the pyrrolopyridine rings. However Wang teaches some of the R4 groups claimed herein as well as those exemplified by the species in the Tables. See definitions of R1-R4 variables on p.12 in the WO publication (or col.8 in US'034) which includes carbamoyl groups, the simplest being CONH2, claimed herein. Thus it would have been obvious to one skilled in the art at the time the invention was made to replace the substituents exemplified by Wang such as

alkoxy, phenyl, alkyl with those instantly embraced and in so doing obtain additional compounds for treating HIV in view of the equivalency teachings outlined above.

While evidence of common ownership may now be enough to disqualify commonly assigned art under 103 based on 102(e) as well as 102(f) or (g) in view of the passage of the American Inventors Protection Act, there must be provided a clear statement by applicants, attorney or agent of record that instant application and USWang **at the time the instant invention was made** were commonly owned. See 1241 OG 96, December 26,2000. However, the WO document would not be excluded.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-5, 7-15,47-49,52,54-61, 63 and 65 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of U.S. Patent No. 6,476,034 . Although the conflicting claims are not identical, they are not patentably distinct from each other because they embrace overlapping subject matter. Compare variables with that claimed herein. The species covered by the claims in US'034 crossread in part with that claimed herein as discussed in the above 102 and 103 rejections.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302). Commonly assigned 6,476,034, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(f) or (g) and

the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee is required under 37 CFR 1.78(c) and 35 U.S.C. 132 to either show that the conflicting inventions were commonly owned at the time the invention in this application was made or to name the prior inventor of the conflicting subject matter. Failure to comply with this requirement will result in a holding of abandonment of the application.

References mentioned in the above rejections have been provided in parent by the examiner or applicants and so not provided herein.

Claims 67-90 and 92 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Bernhardt whose telephone number is (571) 272-0664.

If attempts to reach the examiner by phone are unsuccessful, the supervisor for AU 1624, Dr. Mukund Shah, can be reached at (571)272-0674.

The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

E Bernhardt

EMILY BERNHARDT

PRIMARY EXAMINER

Group 1600